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## CLINICAL RESEARCH

# Safety and effectiveness of drug-eluting stents versus bare-metal stents in elderly patients with small coronary vessel disease



Sécurité d'utilisation et efficacité des stents actifs par rapport aux stents non actifs chez les patients âgés avec des lésions dans les petits vaisseaux coronaires

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### KEYWORDS

Bare-metal stents;  
Drug-eluting stents;  
Elderly patients;  
Percutaneous coronary intervention;  
Small vessel disease

### Summary

**Background.** — Drug-eluting stents (DES) are more effective than bare-metal stents (BMS) in small coronary vessel disease. Whether this is true in elderly patients, it is unclear, as frailty and a high rate of comorbidities could increase the rate of DES-related complications.

**Aims.** — To assess procedural and long-term clinical outcomes of elderly patients with small vessel disease treated with DES or BMS.

**Methods.** — Consecutive elderly patients ( $\geq 75$  years old) treated with stenting of native small coronary arteries (reference vessel diameter and implanted stent  $< 3$  mm) were recruited during 2004–2008. Procedural and long-term clinical outcomes were compared between patients treated with BMS and DES. Propensity score-adjusted logistic regression analysis was performed to account for potential selection bias.

**Abbreviations:** BMS, bare-metal stents; DAPT, dual antiplatelet therapy; DES, drug-eluting stents; IQR, interquartile range; MACE, major adverse cardiac events; MLD, minimal lumen diameter; PCI, percutaneous coronary intervention; SD, standard deviation; TVR, target vessel revascularization.

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**MOTS CLÉS**

Angioplastie  
coronnaire  
percutanée ;  
Patients âgés ;  
Petits vaisseaux ;  
Stent actif ;  
Stent non actif

**Results.** — Among 293 patients (175 BMS, 118 DES), peri-procedural myocardial infarction (12 [7%] vs. 5 [4%];  $P=0.35$ ) and blood transfusions (3 [2%] vs. 0;  $P=0.08$ ) were not significantly different between the BMS and DES groups. Clinical follow-up (96% of patients, median [interquartile range] follow-up 3.5 [2.4] years) showed significantly lower adjusted major adverse cardiac events (hazard ratio [HR] 0.42, 95% confidence interval [CI] 0.24–0.72;  $P=0.002$ ) and target vessel revascularization (TVR) (HR 0.33, 95% CI 0.14–0.76;  $P=0.009$ ) in the DES group. No significant differences were observed between the groups in terms of death, myocardial infarction, stent thrombosis or bleeding.

**Conclusions.** — In this retrospective, non-randomized analysis of the treatment of small vessel disease in elderly patients, DES were as safe and more effective than BMS with a significant reduction in TVR.

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**Résumé**

**Contexte.** — Les stents actifs (SA) sont plus efficaces que les stents non-actifs (SNA) pour traiter les lésions des petits vaisseaux coronaires. Le bénéfice des SA chez les patients âgés sont plus discutés car il s'agit de patients plus fragiles, avec plus de comorbidités et donc plus exposés aux effets indésirables.

**Objectif.** — Évaluer les procédures et le devenir à long-terme des patients âgés avec des lésions dans les petits vaisseaux traités par SA versus SNA.

**Méthodes.** — Tous les patients âgés ( $\geq 75$  ans) avec des lésions primitives dans les petits vaisseaux (diamètre de référence ou stent  $< 3$  mm) traités par angioplastie avec pose de stent ont été recrutés entre 2004 et 2008. Les procédures et le devenir à long-terme ont été comparés selon le type de stent implanté. Une régression logistique et un score de propensité ont été utilisés pour s'affranchir d'éventuels biais.

**Résultats.** — Deux cent quatre-vingt-treize patients ont été inclus (175 SNA, 118 SA). Le nombre d'infarctus (12 [7%] vs 5 [4%];  $p=0,35$ ) et de transfusions (3 [2%] vs 0;  $p=0,08$ ) en post-procédure n'étaient pas différents. Le suivi clinique (96 % des patients, suivi moyen [intervalle interquartile] 3,5 [2,4] ans) a montré moins d'événements cardiovasculaires majeurs (risque relatif [RR] 0,42, 95% intervalle de confiance [IC] 0,24–0,72;  $p=0,002$ ) et moins de revascularisation dans le vaisseau traité (RR 0,33, 95% IC 0,14–0,76;  $p=0,009$ ) chez les patients avec SA. Aucune différence significative n'a été observée entre les groupes concernant les décès, les infarctus, les thromboses de stents et les saignements.

**Conclusions.** — Les SA ne sont pas seulement plus sûres, mais sont aussi plus efficaces que les SNA pour le traitement des lésions dans les petits vaisseaux chez les patients âgés. Le bénéfice clinique à long-terme était principalement lié à la réduction de la revascularisation dans les vaisseaux traités avec les SA.

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**Introduction**

Elderly patients are increasingly being referred for percutaneous coronary intervention (PCI). Yet, due to their increased frailty and higher rate of comorbidities [1–3], they are commonly considered to be at high risk of PCI-related complications and therefore suboptimally treated compared with younger patients [4–6]. Drug-eluting stents (DES), for example, are not implanted due to a hypothetical higher risk of device-related complications (i.e. stent thrombosis or bleeding in the case of premature withdrawal or prolonged dual antiplatelet therapy, respectively). Nevertheless, elderly patients are potentially those who could benefit the most from the use of DES considering the high prevalence of lesion characteristics that increase the restenosis risk, such as multivessel and small coronary artery disease [7,8].

We recently demonstrated, in an all-comer patient population, that DES of small vessel disease is associated with a significant reduction in target vessel revascularization (TVR) compared with bare-metal stenting [9]. This beneficial effect of DES was persistent at long-term follow-up and did not increase the risk of myocardial infarction, stent thrombosis or bleeding. Of interest, a low TVR rate of 17% was noted with the latest generation thin-strut chrome-cobalt BMS. Therefore, their use could be of interest in patients at high risk of bleeding with prolonged dual antiplatelet therapy, such as elderly patients. However, few studies have assessed the efficacy of DES in small vessel disease in elderly patients.

The aim of this retrospective study was therefore to assess the long-term clinical outcome of elderly patients with small vessel disease treated with DES compared with the latest generation thin-strut chrome-cobalt bare-metal stent (BMS).

## Methods

### Patient population

From January 2004 to December 2008, we included consecutive elderly patients ( $\geq 75$  years) treated with PCI and stent implantation of native small coronary vessels. Small vessel disease was defined as a reference vessel diameter  $< 3$  mm (as assessed by quantitative coronary angiography) and/or size of the stent implanted  $< 3$  mm. Patients were excluded if: (1) they were treated with PCI and stenting in another vessel  $> 3$  mm; (2) PCI was performed without stent implantation; (3) PCI was performed on a bypass-graft; or (4) patients received a DES and a BMS in the same vessel. According to the type of stent implanted, patients were divided into BMS and DES groups. If a BMS and a DES were implanted in the same patient, but in different coronary arteries, the patient was assigned to the DES group.

### Coronary angiography and PCI

Coronary angiography and PCI were performed at the physician's discretion based on the clinical indication [10]. The stent implanted (i.e. BMS or DES) was chosen at the operator's discretion. Quantitative coronary angiography was performed to assess stenosis severity using the computer-based analysis system Siemens QuantCor QCA (ACOM.PC 5.01, Siemens Medical Systems Inc, Malvern, Pa). Minimal lumen diameter (MLD), per cent diameter stenosis, reference diameter, and lesion length were measured on end-diastolic angiographic frames. Acute lumen gain was the difference between MLD at the end of the intervention and MLD before balloon dilation. Pharmacological therapy, including platelet inhibitors, during the procedure and at discharge was prescribed according to the current guidelines [11]. BMS were Driver® Coronary System (Medtronic Vascular, Santa Rosa, CA) or PROKinetic® Energy Stent System (BIOTRONIK AG, Bülach, Switzerland). DES were Cypher® Stent (Cordis J&J, Bridgewater, New Jersey), Taxus® Stent (Boston Scientific Corp., Natick, Massachusetts), Endeavor® Stent (Medtronic Vascular, Santa Rosa, CA) and Xience V® Stent (Abbott Vascular, CA, USA).

### Data collection and follow-up

Clinical and procedural data were retrieved from the database of the Cardiovascular Center Aalst OLV Clinic, Aalst (Belgium). Clinical follow-up was carried out for up to 5 years using hospital records and telephone interviews. All events were classified and adjudicated by a physician not involved in the follow-up process. The primary endpoint of the study was major adverse cardiac events (MACE), defined as the composite of overall death, non-fatal re-infarction and TVR (repeated PCI plus coronary artery bypass graft surgery). Secondary endpoints were overall death, myocardial infarction, TVR, stent thrombosis (Academic Research Consortium definitions) and bleeding complications (Thrombolysis in Myocardial Infarction criteria) [12–14]. This study complied with the Declaration of Helsinki and was approved by the local ethical committee. All patients provided written informed consent.

### Statistical analysis

Continuous variables are expressed as mean  $\pm$  standard deviation (SD) or median (interquartile range [IQR]). Categorical variables are reported as frequencies and percentages. Normal distribution was assessed by the Kolmogorov-Smirnov test. Student's *t* test or the Mann-Whitney test was used to compare continuous variables, as appropriate. Comparisons between categorical variables were evaluated using two-tailed Fisher's exact test or Pearson's  $\chi^2$  test, as appropriate. To adjust for potential selection bias, a propensity score was built with a non-parsimonious method by the means of a logistic regression model relating stent group (DES vs. BMS) to pretreatment patient characteristics [15]. Specifically, all the variables listed in Table 1 and the baseline angiographic characteristics included in Table 2 were incorporated into the model and the score was then used in proportional hazards analyses as a covariate. Survival was evaluated by the Kaplan–Meier method and Cox proportional hazard analysis. A *P* value of  $< 0.05$  was considered statistically significant. All analyses were performed with SPSS version 16 (SPSS Inc, Chicago, Ill).

## Results

### Baseline clinical data

Over the inclusion period, 293 elderly patients ( $\geq 75$  years) with small vessel disease undergoing PCI fulfilled the inclusion criteria and were included in the registry: 175 were treated with BMS and 118 with DES. Baseline clinical characteristics are summarized in Table 1. Patients included in the DES group were younger ( $81 \pm 4$  vs.  $82 \pm 4$ ;  $P = 0.007$ ), more likely to have diabetes mellitus (62% vs. 9%;  $P < 0.0001$ ), had a higher body mass index ( $27 \pm 4$  vs.  $26 \pm 4$ ;  $P = 0.02$ ) and were more likely to have had a previous PCI (45% vs. 31%;  $p = 0.01$ ) than those in the BMS group.

### Angiographic and procedural data

Angiographic and procedural characteristics are presented in Table 2. Multivessel PCI, number of vessels treated and mean stents implanted per patient were not significantly different between the two groups. The rates of DES and BMS were similar in all three coronary arteries. Reference vessel diameter, MLD and stent diameter did not differ significantly between the BMS and DES groups. However, lesion length and stent length were significantly higher in the DES group. A trend toward higher acute lumen gain was observed in DES group. The rate of peri-procedural myocardial infarction did not differ between groups (12 [7%] vs. 5 [4%];  $P = 0.35$ ). The zotarolimus-eluting (Endeavor) stent was the most frequently implanted type of DES.

### Clinical follow-up

Clinical follow-up was obtained in 282 of 293 (96%) patients. The median (IQR) follow-up was 3.5 (2.4) years. Unadjusted and propensity score-adjusted analysis results are shown in Table 3; Kaplan–Meier curves are shown in Fig. 1. There was no significant difference in mortality and non-fatal

**Table 1** Baseline clinical characteristics.

	BMS(n = 175)	DES(n = 118)	p
Men	96 (55)	68 (58)	0.64
Age (years)	82 ± 4	81 ± 4	0.007
Body mass index (kg/m <sup>2</sup> )	26 ± 4	27 ± 4	0.02
Ejection fraction (%)	63 ± 17	62 ± 19	0.47
Family history of CAD	40 (23)	30 (25)	0.61
Previous PCI	54 (31)	53 (45)	0.01
Previous CABG	24 (14)	21 (18)	0.34
CVD	16 (9)	13 (11)	0.60
PVD	22 (13)	16 (14)	0.81
Smoking	59 (34)	50 (42)	0.13
Diabetes mellitus	16 (9)	73 (62)	<0.0001
Hypertension	121 (69)	87 (74)	0.40
Hyperlipidaemia	105 (60)	75 (64)	0.54
Clinical presentation			
Stable angina	115 (66)	76 (64)	0.82
UA/NSTEMI	35 (20)	31 (26)	0.21
STEMI	25 (14)	11 (9)	0.20

Data are mean ± standard deviation or number (%).

BMS: bare-metal stent; CABG: coronary artery bypass graft; CAD: coronary artery disease in first-degree relative; CVD: cerebrovascular disease; DES: drug-eluting stent; NSTEMI: non ST-segment elevation myocardial infarction; PCI: percutaneous coronary intervention; PVD: peripheral vascular disease; STEMI: ST-segment elevation myocardial infarction; UA: unstable angina.

**Table 2** Baseline angiographic and procedural characteristics.

	BMS(n = 175)	DES(n = 118)	p
Multivessel PCI	11 (6)	14 (12)	0.09
Number of vessels treated	1.1 ± 0.3	1.1 ± 0.3	0.16
Stents implanted/patient	1.3 ± 0.6	1.4 ± 0.6	0.41
Coronary artery stented <sup>a</sup>			
Left anterior descending	82 (44)	69 (52)	0.14
Left circumflex	72 (39)	45 (34)	0.42
Right coronary artery	33 (18)	18 (14)	0.34
Diameter stenosis (%)	72.0 ± 14.3	73.2 ± 13.1	0.45
RVD (mm)	2.3 ± 0.3	2.2 ± 0.4	0.20
MLD (mm)	0.8 ± 0.3	0.7 ± 0.3	0.07
Lesion length (mm)	13.7 ± 7.5	17.1 ± 7.9	0.02
Stent diameter (mm)	2.6 ± 0.2	2.6 ± 0.1	0.88
Stent length (mm)	21.8 ± 11.8	26.9 ± 14.8	<0.001
Acute lumen gain (mm)	1.4 ± 0.5	1.5 ± 0.5	0.12
Type of DES <sup>b</sup>	—	—	—
ZES	—	62 (41)	—
PES	—	46 (30)	—
EES	—	26 (17)	—
SES	—	17 (11)	—
Other	—	1 (1)	—

Data are mean ± standard deviation or number (%).

BMS: bare-metal stent; DES: drug-eluting stent; RVD: reference vessel diameter; MLD: minimal lumen diameter; ZES: zotarolimus-eluting stent; SES: sirolimus-eluting stent; EES: everolimus-eluting stent; PES: paclitaxel-eluting stent.

<sup>a</sup> 187 and 132 arteries were implanted with BMS and DES, respectively.

<sup>b</sup> 152 DES were implanted.

**Table 3** Clinical events.

Endpoint	Unadjusted				Propensity score adjusted			
	BMS (n = 175)	DES (n = 107)	HR (95% CI) for DES vs BMS	p	HR (95% CI) for DES vs BMS	p	HR (95% CI) for propensity score	p
Death	30 (17)	18 (17)	1.01 (0.56–1.81)	0.97	0.78 (0.38–1.64)	0.52	1.12 (0.92–1.39)	0.26
Non-fatal MI	17 (10)	11 (10)	0.96 (0.44–2.10)	0.93	0.80 (0.30–2.14)	0.66	1.09 (0.83–1.43)	0.53
TVR	34 (19)	11 (10)	0.50 (0.25–0.98)	0.044	0.33 (0.14–0.76)	0.009	1.21 (0.98–1.50)	0.81
MACE	68 (39)	26 (24)	0.61 (0.39–0.96)	0.033	0.42 (0.24–0.72)	0.002	1.20 (1.03–1.38)	0.014
			BMS (n = 175)		DES (n = 107)		HR (95% CI)	p
Death								
Unadjusted								
DES			30 (17)		18 (17)		1.01 (0.56–1.81)	0.97
Propensity score adjusted								
DES							0.78 (0.38–1.64)	0.52
Propensity score							1.12 (0.92–1.39)	0.26
Non-fatal myocardial infarction								
Unadjusted								
DES			17 (10)		11 (10)		0.96 (0.44–2.10)	0.93
Propensity score adjusted								
DES							0.80 (0.30–2.14)	0.66
Propensity score							1.09 (0.83–1.43)	0.53
Target vessel revascularization								
Unadjusted								
DES			34 (19)		11 (10)		0.50 (0.25–0.98)	0.044
Propensity score adjusted								
DES							0.33 (0.14–0.76)	0.009
Propensity score							1.21 (0.98–1.50)	0.81
Major adverse cardiac events								
Unadjusted								
DES			68 (39)		26 (24)		0.61 (0.39–0.96)	0.033
Propensity score adjusted								
DES							0.42 (0.24–0.72)	0.002
Propensity score							1.20 (1.03–1.38)	0.014

BMS: bare-metal stent; CI: confidence interval; DES: drug-eluting stent; HR: hazard ratio; MACE, major adverse cardiac events; MI: myocardial infarction; TVR: target vessel revascularization.

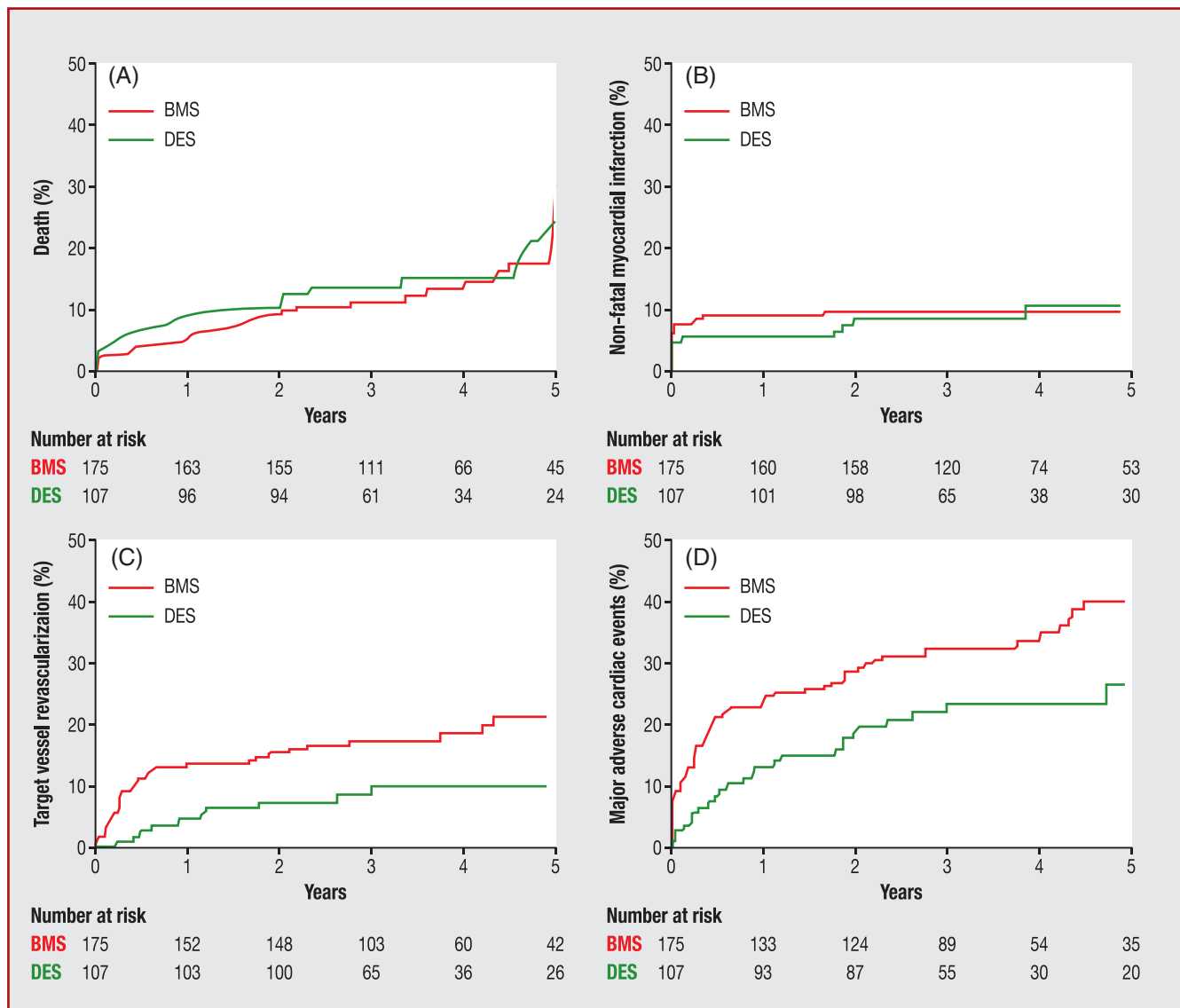
myocardial infarction between groups. However, rates of TVR and MACE were lower in the DES group in both unadjusted and adjusted analyses. The incidence of stent thrombosis was similar in both groups (two patients in each group). There was no significant difference in bleeding complications and only a trend towards more transfusions (3 [2%] vs. 0;  $P=0.08$ ) in the BMS group.

## Discussion

The present retrospective study suggests that DES are safe and more effective than the latest-generation BMS in reducing TVR and MACE at long-term follow-up in elderly patients with small vessel disease. The number of elderly patients referred to PCI is increasing rapidly [1–3]. Age is a major determinant of clinical outcomes in patients with coronary artery disease [1–6], and elderly patients are considered at higher risk of ischaemic and bleeding complications. These

factors, frailty and a higher rate of comorbidities [1–3] leads to suboptimal treatment of elderly patients [4–6]: they are, for example, often denied novel and more effective technologies, as suggested by their exclusion or low rate of inclusion in randomized clinical trials [16].

Elderly patients often present with multivessel and small coronary artery disease (58–69%) [1–3]. These anatomical characteristics are predictive of restenosis, which can be prevented by the use of DES [7,8,17]. Nevertheless, scarce data on long-term safety and efficacy of DES are available in elderly patients. Two single-centre observational studies have reported that DES in elderly patients are as safe as BMS [18,19]. Recently, in the largest series of elderly patients treated with PCI, Wang et al. reported that DES were associated with a superior long-term clinical benefit than BMS [3]. None of these studies specifically focused on small vessel disease, nor did they demonstrate a significant reduction of repeat revascularization in elderly patients treated with DES. The lack of anti-restenotic effect of DES was partly



**Figure 1.** Kaplan–Meier curves for overall mortality (A), non-fatal MI (B), TVR (C) and MACE (D) at 5-year follow-up. BMS: bare-metal stent; DES: drug-eluting stent; MACE: major adverse cardiac events; MI: myocardial infarction; TVR: target vessel revascularization.

attributed to the lower use of revascularization in elderly patients, which may lead to underestimation of the benefit of DES on repeat revascularization. Alternatively, this could also be due to the improved performance of latest generation thin-strut chrome-cobalt BMS.

We recently reported a low (17%) TVR rate in all-comer patients with small vessel disease treated with contemporary BMS [9]. These data were also replicated in the current study conducted in elderly patients with small vessel disease where we observed a 19% TVR rate with BMS. In addition, we confirmed that the clinical benefit of DES in elderly patients with small vessel disease is mostly driven by a reduction in TVR. This favourable outcome was obtained despite the higher incidence of diabetes in the DES group. This uneven treatment allocation is mainly explained by the Belgian reimbursement policy at the time of the study recruitment that restricted reimbursement of DES to diabetic patients. To account for this heterogeneity, we performed propensity score-adjusted analyses that confirmed a 67% TVR reduction

and a 58% reduction of MACE with DES. Finally, the safety profile of DES was similar to that of BMS with no difference in bleeding, need for blood transfusion, peri-procedural myocardial infarction or stent thrombosis.

Currently, the main limitation of DES in elderly patients is the need for prolonged dual antiplatelet therapy (DAPT), especially in patients at high risk of bleeding. However, recent data suggests that a shorter period of DAPT with DES may be sufficient. A randomized clinical trial between a drug-coated stent and BMS (Leaders Free, NCT01623180) that is assessing the potential for delivering the anti-restenotic benefit of a DES with a shorter course of DAPT in patients at high risk of bleeding will provide important information. This ongoing study could potentially change our clinical practice by facilitating a short DAPT duration (1 month) in patients who may not be suitable for longer courses of treatment.

As in all retrospective observational investigations, our study is limited by its non-randomized nature. Also, the



definition of elderly in our study was age  $\geq 75$  years, while other studies have chosen a higher limit, e.g. 80 years. Our lower age limit could have reduced our event rates, but despite including a wider range of ages, the size of our population is relatively small. In addition, the reasons for choosing a DES or BMS were at the operator's discretion and were not gathered prospectively. We noted differences in clinical and procedural characteristics between groups. However, our findings reflect clinical practice. To minimize for potential bias due to uncontrolled treatment allocation, we performed a propensity score adjusted analysis. Of note, DES were still associated with improved outcome despite more unfavourable clinical and procedural characteristics.

Another limitation of our study is the possible under-reporting of some events (i.e. minor bleedings) at clinical follow-up. Compliance to DAPT after PCI might potentially influence long-term bleeding risk in these elderly patients. At 1 year, 35 (20%) patients in the BMS group and 80 (75%) patients in the DES groups ( $P < 0.001$ ) were taking DAPT. Unfortunately, we did not collect this information at the latest clinical follow-up. However, taking into account the above-mentioned under-reporting issue, we did not observe any significant difference between the two groups in terms of bleeding.

The definition of small vessel disease varies from study to study and is based primarily on the pre-PCI angiographic estimation of reference vessel diameter ( $< 2.8$  to  $3.0$  mm) [20–22]. Other studies have chosen to define vessels as small if the stent diameter was  $< 3.0$  mm [23]. Although we acknowledge the limitation of a classification based exclusively on angiographic data, we minimized potential misclassification by including only vessels with a reference vessel diameter and a stent size  $< 3$  mm.

## Conclusions

In elderly patients, PCI of small vessel disease represents a challenge for interventional cardiologists. In this retrospective, non-randomized analysis on the treatment of small vessel disease in elderly patients, DES were as safe as and more effective than BMS, with a significant reduction in the rate of TVR.

## Disclosure of interest

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